

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

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**IN RE: JOHNSON & JOHNSON  
TALCUM POWDER PRODUCTS  
MARKETING, SALES  
PRACTICES, AND PRODUCTS  
LIABILITY LITIGATION**

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**MDL No. 16-2738 (MAS) (RLS)**

***THIS DOCUMENT RELATES TO  
ALL CASES***

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**THE PLAINTIFFS' STEERING COMMITTEE'S BRIEF REGARDING  
THE RULE 702 STANDARD**

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Chief Judge Wolfson made rulings on the admissibility of the parties' general causation experts in an April 27, 2020 Opinion. This Court is permitting new challenges to those rulings where it can be shown that the "Opinion demonstrably fails to adhere to [clarified] Rule 702" or "new science is shown to directly contradict or challenge" the rulings.<sup>1</sup> However, there is no new science that contradicts or challenges Plaintiffs' experts' opinions or Judge Wolfson's rulings related to those opinions.

Further, neither Rule 702's amendments, nor recent case law since adoption of the amendments, have changed the fundamental requirements for admissibility of expert evidence. The *Daubert* factors and the standard for admissibility remain the same as they were at the time of Judge Wolfson's Opinion and Order. The Court's rulings resulted from a faithful application of the *Daubert* standards and Rule 702, and they withstand scrutiny.<sup>2</sup>

## I. **GENERAL CAUSATION EXPERT ADMISSIBILITY**

In *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), the United States Supreme Court outlined standards for admitting expert testimony, which are incorporated into Fed. R. Evid. 702. According to the rule, a qualified expert

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<sup>1</sup> Memorandum Order, ECF No. 32122 (April 30, 2024).

<sup>2</sup> This Brief incorporates by reference the Plaintiff Steering Committee's Response To The Court's April 30, 2024 Memorandum and Order Regarding Judge Wolfson's *Daubert* Opinion On General Causation (filed contemporaneously), which sets forth Plaintiffs' analysis of the scientific evidence and expert opinion evaluated in Judge Wolfson's April 27, 2020 Opinion and the scientific evidence that has been published or developed since that time.

witness may testify “if the proponent demonstrates to the court that it is more likely than not that:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert’s opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702. As gatekeeper for expert evidence, the trial court’s role is to ensure that the expert testimony is both relevant and reliable.<sup>3</sup> In the Third Circuit, the three fundamental Rule 702 inquiries are qualification, reliability, and fit.<sup>4</sup> The proponent of the evidence must show that its reliability, not its correctness, passes the admissibility test by a preponderance of the evidence.<sup>5</sup>

#### **A. There Is A Three-Part Process For Testing Expert Evidence In The Third Circuit**

In the Third Circuit, an inquiry under Fed. R. Evid. 702 has three parts: qualifications, reliability, and fit.<sup>6</sup>

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<sup>3</sup> See *O’Bryant v. Johnson & Johnson*, No. 20-2361, 2022 WL 7670296, at \*3 (D.N.J. Oct. 13, 2022) (unpublished) (Shipp, J.) (citing *Daubert v. Merrill Dow Pharms. Inc.*, 509 U.S. 579, 597 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-48 (1999)).

<sup>4</sup> *Id.* (citing *United States v. Schiff*, 602 F.3d 152, 172 (3d Cir. 2010)).

<sup>5</sup> *Id.* (citing *Mahmood v. Narciso*, 549 F. App’x 99, 102 (3d Cir. 2013)). See also *Nichols v. Morrisey*, No. 2:23-CV-00637, 2024 WL 871322, at \*1 (E.D. Pa. Feb. 29, 2024) (expert testimony must be proven admissible by a preponderance of the evidence) (citing *In re: TMI Litig.*, 193 F.3d 613, 705 (3d Cir. 1999)).

<sup>6</sup> *Calhoun v. Yamaha Motor Corp., USA*, 350 F.3d 316, 321 (3d Cir. 2003) (citations omitted).

## **1) Qualifications**

Initially, the expert must be qualified, *i.e.*, have specialized knowledge on the topic at issue.<sup>7</sup> It is not necessary for the expert to be the best qualified.<sup>8</sup> Further, the qualification requirements should not be “overly rigorous.”<sup>9</sup>

## **2) Reliability**

The trial court must determine that the expert’s testimony is reliable.<sup>10</sup> An expert’s opinion must rest on “good grounds” and be produced by the scientific method.<sup>11</sup> A court has significant latitude in deciding the reliability of expert testimony.<sup>12</sup> Several factors play a role in the reliability analysis:

[(1)] whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or

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<sup>7</sup> *In re: Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994). See also *Raritan Baykeeper Inc. v. NL Indus., Inc.*, No. 09-4117, 2017 WL 3568401, at \*2 (D.N.J. Aug. 16, 2017).

<sup>8</sup> *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008).

<sup>9</sup> *Allen v. Foxway Transp., Inc.*, No. 4:21-CV-00156, 2024 WL 388133, at \*2 (M.D. Pa. Feb. 1, 2024).

<sup>10</sup> *In re: Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994) (“This does not mean that plaintiffs have to prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of the evidence that their opinions are *reliable*.” (emphasis in original) (italics added)).

<sup>11</sup> *In re: Proton-Pump Inhibitor Prod. Liab. Litig.*, No. 2:17-MD-2789, 2022 WL 18999830, \*5 (D.N.J. Jul. 5, 2002) (quoting *Daubert*, 509 U.S. at 592). See also *Burns v. SeaWorld Parks & Entertainment, Inc.*, No. 22-2941, 2024 WL 710631, at \*4 (E.D. Pa. Feb. 21, 2024) (“*Daubert* requires that the expert have ‘good grounds’ for their belief and that the opinion is based on the ‘methods and procedures of science.’”) (quoting *In re: Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994)).

<sup>12</sup> *In re: Valsartan, Losartan, and Irbsartan Prods. Liab. Litig.*, No. 19-2875, 2024 WL 65132, at \*3 (D.N.J. Jan. 5, 2024) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)).

potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses.<sup>13</sup>

This flexible inquiry “must focus solely on the expert’s chosen principles and methodology rather than the conclusions drawn from them.”<sup>14</sup>

Reliability has a lower evidentiary requirement than the merits standard of correctness, and it is not necessary for a judge to think that an expert is correct.<sup>15</sup> “The opinion does not need to have the strongest evidentiary foundation or be ‘supported by the best methodology or unassailable research’ to survive a *Daubert* motion.”<sup>16</sup> Though a court must review the expert’s methodology and application of the methodology, it should not “usurp the role

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<sup>13</sup> *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003).

<sup>14</sup> *Bavone v. Primal Vantage Co., Inc.*, \_\_\_ F. Supp. 3d \_\_\_, 2024 WL 756815, at \*4 (W.D. Pa. Feb. 21, 2024) (citing *Daubert*, 509 U.S. at 594-95). See also *Silipena v. American Pulverizer Co.*, No. 16-711, 2024 WL 3219226, at \*3 (D.N.J. June 28, 2024) (“With respect to reliability, the focus is on the ‘principles and methodology, not on the conclusions that they generate.’”) (quoting *Daubert*, 509 U.S. at 595).

<sup>15</sup> *Valsartan*, 2024 WL 65132 at \*3 (quoting *Paoli*, 35 F.3d at 744-45) (internal quotations omitted).

<sup>16</sup> *In re: Proton Pump Inhibitor*, 2022 WL 18999830, at \*6 (quoting *In re: TMI Litig.*, 193 F.3d at 665). See also *Burns v. Seaworld Parks & Entertainment, Inc.*, No. 22-2942, 2024 WL 710631, at \*6 (E.D. Pa. Feb. 21, 2024) (“An expert’s methodology ‘does not have to obtain general acceptance or be subject to peer review to be admitted under Rule 702’”) (quoting *Schneider*, 320 F.3d at 806).

of the fact-finder, instead an expert should only be excluded if ‘the flaw is large enough that the expert lacks the ‘good grounds’ for his or her conclusion.’<sup>17</sup>

### 3) Fit

“As for relevance or fit, expert testimony must have a tendency to make the existence of any fact of consequence to the determination of the task at hand more probable or less probable than it would be without the evidence.”<sup>18</sup> There must be a connection between the proffered evidence and specific factual issues in dispute.<sup>19</sup>

## **B. The Court Is Tasked With Determining The Reliability Of An Expert’s Methodology, Not The Correctness Of The Expert’s Conclusions**

When deciding whether to admit expert testimony, the Court examines the reliability of “the methodology, the facts underlying the expert’s opinion, and the link between the facts and the conclusion.”<sup>20</sup> The proponents of the testimony are required to show *reliability* by a preponderance of the evidence.<sup>21</sup> However, whether the expert’s testimony is credible—carries weight or is correct—is not resolved by the court in deciding a motion to preclude, but is for the fact-finder

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<sup>17</sup> *In re: Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 792-93 (3d Cir. 2017).

<sup>18</sup> *Valsartan*, 2024 WL 65132, at \*2 (citing *Amorgianos*, 303 F.3d at 265).

<sup>19</sup> *Bavone*, 2024 WL 756815, at \*4 (citing *In re: Paoli*, 35 F.3d at 743). See also *Schneider*, 320 F.3d at 404 (“[R]ule 702 requires that the expert testimony must fit the issues in the case.”).

<sup>20</sup> *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012).

<sup>21</sup> *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000).

to determine.”<sup>22</sup>

Dueling interpretations of certain evidence is the type of matter left for a jury to decide.<sup>23</sup> In the face of competing scientific theories, the trial court may not rule on which is right.<sup>24</sup> The jury must make that decision when the court has found that “the expert’s testimony falls within ‘the range where experts may reasonably differ.’”<sup>25</sup>

## **II. DEFENDANTS HAVE NO BASIS TO CHALLENGE THE DAUBERT RULINGS**

### **A. There Was No “Incorrect Application of Rule 702”**

Federal Rule of Evidence 702 was recently amended, effective December 1, 2023. According to the Advisory Committee Notes, the amendments are meant “to clarify and emphasize that expert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that

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<sup>22</sup> *Valsartan*, at \*3 (citing *Kannankeril*, 128 F.3d at 810).

<sup>23</sup> *O’Bryant*, 2022 WL 7670296, at \*9 (citing *Cadmus v. Aetna Cas. & Surety Co.*, 1996 WL 652769, at \*2 (6th Cir. Nov. 7, 1996 (unpublished)). See also *Nichols*, 2024 WL 871322 (“In any case, the respective credibility of dueling experts is a matter for the jury.”).

<sup>24</sup> *Milward v. Acuity Specialty Prod. Grp., Inc.*, 639 F.3d 11, 15 (1st Cir. 2011) (internal quotation marks and citations omitted).

<sup>25</sup> *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153 (1999); *In re: Urethane Antitrust Litig.*, 166 F. Supp. 3d 501 (D.N.J. 2016) (“in serving the ‘gatekeeper function’ and assessing the reliability of an expert’s methodology, the Court must be mindful that in order to be admissible, a scientific method need not be the ‘best’ method or one that is demonstrably correct. ‘Rather, the test is whether the ‘particular opinion is based on valid reasoning and reliable methodology.’”)

the proffered testimony meets the admissibility requirements set forth in the rule.”<sup>26</sup> The amendment did not change the rule’s substantive requirements.<sup>27</sup>

No new procedures or standards were imposed by the amendment. “Rather, the amendment is simply intended to clarify that Rule 104(a)’s requirement applies to expert opinions under Rule 702.”<sup>28</sup> Further, “nothing in the amendment requires the court to nitpick an expert’s opinion in order to reach a perfect expression of what the basis and methodology can support.”<sup>29</sup> The Advisory Committee believed that some courts were incorrectly applying the reliability requirements of Rule 702.<sup>30</sup> That is not what happened with Judge Wolfson’s Opinion. To the contrary, Judge Wolfson fully analyzed the proffered testimony and applied 702’s requirements, and the amendments do not affect the analysis and conclusions.

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<sup>26</sup> Adv. Com. Notes to Rule 702 (2023).

<sup>27</sup> See *Johnson v. Comodo Grp., Inc.*, No. 2:16-04469, 2024 WL 2933195, at \*4 n.6 (D.N.J. June 10, 2024) (unpublished) (“The amendment does not substantively alter Rule 702 but rather ‘clarifies that the preponderance standard applies to the three reliability-based requirements added in 2000—requirements that many courts have incorrectly determined to be governed by the more permissive Rule 104(b) standard.’”) (quoting Adv. Com. Notes to Rule 702 (2023); *Walden v. Bank of N.Y. Mellon Corp.*, No. 2:20-CV-01972, 2024 WL 343087, at \*2 n.3 (W.D. Pa. Jan. 30, 2024) (*Daubert* legal standard not substantively changed by 2023 amendment); *Costello v. Mountain Laurel Assur. Co.*, No. 2:22-CV-35, 2024 WL 239849, at \*4 (E.D. Tenn. Jan. 22, 2024) (“these amendments were intended to clarify the requirements of the Rule, not to make substantive changes.”)).

<sup>28</sup> Adv. Com. Notes to Rule 702 (2023).

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

**B. Judge Wolfson Applied The Proper Standard – Preponderance of the Evidence**

Judge Wolfson's clear application of Rule 702's preponderance standard is undeniable.<sup>31</sup> Judge Wolfson never indicated that the admissibility of expert evidence should be tested by any standard other than preponderance of the evidence. In fact, the opinion has been cited for stating that the proffering party's burden is preponderance of the evidence.<sup>32</sup> Further, the preponderance standard was referenced by the PSC in the *Daubert* briefing.<sup>33</sup> It is unnecessary for a Court to repeatedly state a standard to prove that the standard is being applied. It is clear from Judge Wolfson's meticulous examination of the evidence and the detailed analysis of the issues that she used the preponderance of the evidence standard in her *Daubert* analysis.

None of Judge Wolfson's findings are undermined by the amendments to Rule 702. Judge Wolfson's analysis and rulings are valid under the amended

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<sup>31</sup> See *In re: Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig.*, 509 F. Supp. 3d 116, 147-48, 187 (D.N.J. 2020) (citing case law referencing the proponents' "burden of establishing admissibility by a preponderance of the evidence.").

<sup>32</sup> See *Visakay v. Sears Roebuck and Co.*, No. 2:17-cv-11570, 2024 WL 1855051, at \*2 (D.N.J. April 29, 2024) ("the party offering the expert testimony has the burden of proof by a preponderance of the evidence.") (citing *In re: Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Prods. Litig.*, 509 F. Supp. 3d 116, 147–48 (D.N.J. 2020); *In re: Hum. Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 655 (D.N.J. 2008)).

<sup>33</sup> *The Plaintiffs' Steering Committee's Omnibus Brief Regarding Daubert Legal Standard And Scientific Principles For Assessing General Causation*, ECF No. 9732 at 2 n.5, 6 n.21 (May 7, 2019).

Rule 702, as those amendments did not change the long-standing standard under which she decided the *Daubert* issues.

**C. Judge Wolfson's Rulings Regarding Weight of the Evidence Remain Proper Under Revised Rule 702**

Historically, challenges to expert evidence have included questions that courts have properly reserved for the trier-of-fact, as they are matters of the weight of evidence. “The fact that an expert’s opinion is contradicted or disputed by other evidence in the record does not necessarily warrant exclusion of the expert’s opinion. Contrary evidence goes to the weight, and not the admissibility, of the expert testimony.”<sup>34</sup> The recent amendments to Rule 702 do not change that. To the extent that Judge Wolfson ruled that some of the Defendants’ challenges to Plaintiffs’ experts raised questions that went to weight versus admissibility, those rulings remain proper under the revised Rule 702.

According to the Advisory Committee, “Some challenges to expert testimony will raise matters of weight rather than admissibility even under the Rule 104(a) standard. For example, if the court finds it more likely than not that an expert has a sufficient basis to support an opinion, the fact that the expert has not read every single study that exists will raise a question of weight and not admissibility . . . it means that once the court has found it more likely than not

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<sup>34</sup> *O'Bryant*, 2022 WL 7670296, \*9 (quoting *Mims v. Wright Med. Tech., Inc.*, No. 11-213, 2012 WL 12835870, at \*2 (N.D. Ga. May 11, 2012)).

that the admissibility requirements has been met, any attack by the opponent will go only to the weight of the evidence.”<sup>35</sup>

#### **D. Judge Wolfson Completed A Full *Daubert* Analysis Of The Experts**

##### **1) Bradford Hill Analyses**

The scientific community uses the nine-factor Bradford Hill method to assess general causation.<sup>36</sup> “Those nine factors are (1) temporal relationship; (2) strength of association; (3) dose-response relationship; (4) replication; (5) biological plausibility; (6) consideration of alternative explanation; (7) cessation of exposure; (8) specificity of the association; and (9) consistency with other knowledge.”<sup>37</sup>

“To ensure that the Bradford Hill/weight of the evidence criteria ‘is truly a methodology, rather than a mere conclusion-oriented selection process... there must be a scientific method of weighting that is used and explained.’ For this reason, the specific techniques by which the weight of the evidence/Bradford Hill methodology is conducted must themselves be reliable according to the principles articulated in *Daubert*.<sup>38</sup> Judge Wolfson carefully examined the experts’ Bradford Hill analyses to make sure that “the ‘techniques’ used to

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<sup>35</sup> Adv. Com. Notes to Rule 702 (2023).

<sup>36</sup> *In re: J&J*, 509 F. Supp. 3d at 160 (citation omitted).

<sup>37</sup> *Id.* at 161 (citing Michael D. Green, et al., *Reference Guide on Epidemiology, In reference Manual on Scientific Evidence* 549, 600 (Fed. Jud. Ctr., 3d ed. 2011)).

<sup>38</sup> *Zoloft*, 858 F.3d at 796 (quoting *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 602, 607 (D.N.J. 2002)).

implement the [Bradford Hill] analysis [were] 1) reliable and 2) reliably applied.”<sup>39</sup>

**a. *Strength of association***

Judge Wolfson found that the experts gave good grounds for their weighing of the strength of association factor, and the Defendants did not provide “any compelling grounds for the Court to find otherwise.”<sup>40</sup> “Defendants may present their arguments on whether the association is ‘weak’ or ‘strong’ to the jury, as that is a matter of weight not reliability.”<sup>41</sup> Judge Wolfson examined the experts’ opinions and the reasoning for the weight given to the strength of association factor. She first answered the question of reliability, and then properly found that Defendants’ arguments went to the weight of the testimony, not admissibility.

Dr. McTiernan, Dr. Carson, and Dr. Clarke-Pearson explained how they reviewed studies, and why they gave more weight to case-control studies than cohort studies. Judge Wolfson found that the experts did not ignore cohort studies, and that they had good grounds for relying on case-control studies.<sup>42</sup> “In the end, Defendants may disagree with the experts’ interpretations of those

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<sup>39</sup> *In re: J&J*, 509 F. Supp. 3d at 161 (quoting *In re: Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 795 (3d Cir. 2017)).

<sup>40</sup> *Id.* at 163.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.* at 166 (relying on *In re: Roundup Prods. Liab. Litig.*, 390 F. Supp. 3d 1102 (N.D. Cal. 2018)).

studies and their usefulness, but such issues go the weight of the experts' testimony, and not their reliability.”<sup>43</sup>

Judge Wolfson also addressed Defendants' arguments regarding the consideration of confounding and recall bias in case-control studies, finding that the experts “accounted for these external circumstances and factors.”<sup>44</sup> Defendants' arguments regarding Plaintiffs' experts' assessment of recall bias and potential confounders reveal disagreements with conclusions, not methodology, and thus, don't undermine the experts' reliability.<sup>45</sup>

### **b. *Consistency***

“The consistency factor considers whether the results of the relied upon studies have been replicated.”<sup>46</sup> Defendants disputed “the role that statistical significance plays in determining the consistency of epidemiological studies.”<sup>47</sup> Judge Wolfson noted that in *In re: Zoloft*, the Third Circuit declined to adopt a bright-line rule regarding “the role of statistical significance in proving causality.”<sup>48</sup> The causation experts' consideration of statistical significance

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<sup>43</sup> *Id.* at 166-67 (citing *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414-15 (3d Cir. 2002)).

<sup>44</sup> *Id.* at 167.

<sup>45</sup> *Id.* at 168 (citing *Walker v. Gordon*, 46 F. App'x 691, 694 (3d Cir. 2002)).

<sup>46</sup> *Id.*

<sup>47</sup> *Id.* at 169.

<sup>48</sup> *Id.* at 170. See *In re: Zoloft*, 858 F.3d at 793 (“A causal connection may exist despite the lack of significant findings, due to issues such as random misclassification or insufficient power. Conversely, a causal connection may not exist despite the presence of significant findings.” Thus, while statistical significance is valuable factor, its importance should not be overstated or understated.).

regarding both cohort and case control studies met the reliability test.<sup>49</sup> This finding was proper, as, again, it is not the trial court's job to choose which party is right regarding the science. *Daubert* law is clear that such matters are for the trier of fact to decide.

### **c. Biological Plausibility**

The biological plausibility factor looks at “whether the purported association [is] biologically plausible and consistent with existing scientific knowledge.”<sup>50</sup> “[B]iological plausibility does not require certainty or even proof for the biological mechanism in question – the relevant question is ‘whether the hypothesized causal link is credible in light of what is known from science and medicine about the human body and the potentially offending agent.’”<sup>51</sup> “The fact that there remains debate in the scientific community as to the mechanism(s) by which talc migrates to the ovaries does not preclude admission of the experts’ theory.”<sup>52</sup>

Judge Wolfson ruled that Plaintiffs’ experts can “testify that it is biological plausible that talc can lead to chronic inflammation, which in turn increases the risk of ovarian cancer.”<sup>53</sup> “The hypothesis is based on scientific

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<sup>49</sup> *Id.*

<sup>50</sup> *Id.* (citing Green, at 604).

<sup>51</sup> *Id.* at 174 (quoting *Milward*, 639 F.3d at 25).

<sup>52</sup> *Id.* (citing *In re: Fosamax Prods. Liab. Litig.*, 643 F. Supp. 2d 164, 183 (S.D.N.Y. 2009); *In re: PPA*, 289 F. Supp. 2d at 1247).

<sup>53</sup> *Id.* at 175. Judge Wolfson excluded testimony from Plaintiffs’ experts regarding the inhalation theory for talc reaching the ovaries, finding that they had not provided adequate scientific basis for that theory. *Id.* at 176.

research and reasoning. Contrary to Defendants' position, the fact that the mechanism has not been *proven* does not negate the reliability of the experts' opinion on this issue." Again, the Court carefully examined the evidence and found that it met the reliability standard.

**d. Dose Response**

"Under Bradford Hill, the dose response factor considers whether there is a 'dose-response relationship,' meaning 'that the greater the exposure, the greater the risk of disease.'"<sup>54</sup> Judge Wolfson noted that "based on epidemiological principles, a strong dose-response is not necessarily required for an expert to find a causal nexus."<sup>55</sup> The experts' conducted a meta-analysis and explained the reliability of the studies.<sup>56</sup> Again, the Court found that Defendants' argument with the experts boiled down to "competing interpretations of the studies' results and whether those results support a dose-response relationship," but as long as there are good grounds for the interpretations, the gatekeeper is not tasked with deciding which is correct.<sup>57</sup>

**e. Specificity**

According to the specificity factor, "[a]n association exhibits specificity if the exposure is associated only with a single disease or type of disease."<sup>58</sup>

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<sup>54</sup> *Id.* at 177 (quoting Green at 603).

<sup>55</sup> *Id.* at 179 (citing *Ferguson v. Riverside Sch. Dist.* No. 416, No. 00-0097, 2002 WL 34355958, \*6 (E.D. Wash. Feb. 5, 2002)).

<sup>56</sup> *Id.* (citing Green, at 603).

<sup>57</sup> *Id.* (citing *Stecyk*, 295 F.3d at 414-15).

<sup>58</sup> *Id.* (citing Green, at 605).

“While ‘evidence of specificity may strengthen the case of causation, lack of specificity does not necessarily undermine it where there is a good biological explanation for its absence.’”<sup>59</sup> The Court found that Plaintiffs’ experts based their opinions “on good grounds and considered scientific evidence to conclude that the association is specific to ovarian cancer.”<sup>60</sup>

**f. *Temporality***

“It is well-established that ‘[a] temporal, or chronological, relationship must exist for causation to exist,’ *i.e.*, the exposure must have occurred before the disease develops.”<sup>61</sup> This was a highly weighted factor for Plaintiffs’ general causation experts. Judge Wolfson determined that “Defendants’ argument does not present a question of reliability—but scientific disagreement.”<sup>62</sup>

**g. *Coherence***

“Under Bradford Hill, the coherence factor ensures that the association (talc and ovarian cancer) does not conflict with other known scientific facts, *i.e.*, coherence with existing knowledge of the development of the disease (ovarian cancer) in question.”<sup>63</sup> Plaintiffs’ experts’ theory is that inflammation caused by

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<sup>59</sup> *Id.*

<sup>60</sup> *Id.* at 181.

<sup>61</sup> *Id.* (citing Green, at 601).

<sup>62</sup> *Id.*

<sup>63</sup> *Id.* at 182.

talc leads to ovarian cancer.<sup>64</sup> Defendants' arguments on this factor go "beyond whether the experts' opinions were reached using sound methodology."<sup>65</sup>

#### ***h. Experiment***

This factor "considers whether there is experimental evidence to support the association."<sup>66</sup> "The experts generally did not afford this factor great weight because of the ethical implications for conducting a randomized trial on women to explore the relationship between talc use and ovarian cancer."<sup>67</sup> Defendants' argument that contradictory studies don't support causation "is a question of weight for the jury to decide." Defendants again asserted their disagreement about study interpretation, which is not a sufficient basis for questioning reliability.<sup>68</sup>

#### ***i. Analogy***

"[T]he analogy factor of Bradford Hill provides that '[s]ubstantiation of relationships similar to the putative causal relationship increases the likelihood of causation.'"<sup>69</sup> "On this factor, the general causation experts compare the relationship between talc and ovarian cancer to the relationship between asbestos and the development of ovarian and lung cancer."<sup>70</sup> This factor is not

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<sup>64</sup> *Id.*

<sup>65</sup> *Id.* at 183-84 (citing *Daubert*, 509 U.S. at 596).

<sup>66</sup> *Id.* at 184.

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* (citing *Stecyk*, 295 F.3d at 414-15).

<sup>69</sup> *Id.* (quoting *In re: Mirena Ius Levonorgestrel-Related Prods. Liab. Litig. (No. II)* ("Mirena II"), 341 F. Supp. 3d 213, 243 (S.D.N.Y. 2018)).

<sup>70</sup> *Id.*

required to prove causation. “[T]he experts’ comparison of asbestos and talc is based on these minerals’ tendency to cause inflammation, which could lead to carcinogenesis.”<sup>71</sup> Judge Wolfson could not find that the comparison was unreliable.<sup>72</sup>

## 2) Dr. Longo

All of Judge Wolfson’s rulings regarding Dr. Longo’s TEM analysis resulted from applying the proper Rule 702 standard. Judge Wolfson first found that the three-step TEM method used by Dr. Longo was reliable as “a generally accepted method in the scientific community.”<sup>73</sup> Dr. Longo’s opinions were based on a generally accepted scientific method, and his application of the methodology was reliable. Judge Wolfson found that this expert evidence met the preponderance of the evidence standard for reliability.<sup>74</sup> She also properly found that disagreements between dueling experts over specific testing protocols were reserved for presentation to the trier of fact as matters of weight, not admissibility. As the amendments to Rule 702 do not create new standards, Judge Wolfson’s rulings should remain in effect.

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<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> *In re: J&J*, 509 F. Supp. 3d at 148.

<sup>74</sup> Judge Wolfson ruled that Dr. Longo cannot testify to polarized light microscopy (PLM) testing for amphibole asbestos. *In re: J&J*, 509 F. Supp. 2d at 155, 157. The PLM testing for amphibole asbestos is distinct from the testing Dr. Longo conducted of Johnson’s Baby Powder and Shower to Shower for chrysotile asbestos. Dr. Longo’s PLM testing results for chrysotile asbestos were disclosed in November 2023, years after the original order.

**E. New Science Neither Challenges Nor Contradicts Judge Wolfson's *Daubert* Rulings On Plaintiffs' Experts**

No new or emergent science warrants disputing Judge Wolfson's rulings on the admissibility of Plaintiffs' experts. In fact, Plaintiffs' experts' opinions have been affirmed.<sup>75</sup> Scientific studies published since 2020 affirm the reliability of Plaintiffs' experts' methodology and the application of that methodology to the facts in this case. Nor does any new science subvert Judge Wolfson's painstaking *Daubert* analysis, in which she applied the relevant preponderance standard and found that the general causation testimony of Plaintiffs' experts is admissible.

**F. Recent *Daubert* Decisions Do Not Undermine Judge Wolfson's Admission of Plaintiffs' Experts**

Recent *Daubert* decisions do not undermine Judge Wolfson's findings. For example, *In re: Tasigna (Nilotinib) Prod. Liab. Litig.*, No. 6:21-md-3006, 2024 WL 1343157 (M.D. Fla. Jan. 15, 2024), the challenged expert had relied on epidemiological studies for his general causation opinion re: Tasigna causing severe atherosclerotic injuries.<sup>76</sup> Novartis did not attack the expert's methodology, but rather alleged flaws in the underlying clinical trials. Such arguments go to weight of the expert's opinion, not admissibility.<sup>77</sup> The court

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<sup>75</sup> See Plaintiffs' Steering Committee' Response To The Court's April 30, 2024 Memorandum and Order Regarding Judge Wolfson's *Daubert* Opinion On General Causation (filed contemporaneously).

<sup>76</sup> *In re: Tasigna*, 2024 WL 1343157, at \*5.

<sup>77</sup> *Id.* at \*4 (citations omitted).

correctly found that the expert’s methodology was sufficiently reliable because the expert “properly identifies each of the Bradford Hill factors, isolates them, and explains what they are. He then applies the data from his association conclusion to assess how well each factor shows causation. While [the expert] need not have analyzed all nine factors to reach his conclusion, he did.”<sup>78</sup> Though he did not rank the factors, such a ranking is not required to show reliability.<sup>79</sup> As a result, the expert’s general causation opinion was largely admitted.<sup>80</sup>

In *Feindt v. United States*, No. CV 22-00397, 2024 WL 1532747 (D. Haw. Apr. 9, 2024), the court noted its broad latitude in assessing expert reliability. Despite the expert’s lack of explanation “for his conclusion that the factors of temporality and coherence are met” or his process for “weighing and evaluating evidence for each of the Bradford Hill criterion,” his general causation opinions passed the reliability test and were admissible.<sup>81</sup> “Challenges to his opinion will be left to cross examination, contrary evidence, and attention to the burden of proof at trial.”<sup>82</sup>

Plaintiffs’ experts in *Gonzales v. BNSF Railway Co.*, No. 1:21-cv-01690, 2024 WL 836793 (D. Col. Jan. 25, 2024), were found to have reliable opinions.

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<sup>78</sup> *Id.* (citations omitted).

<sup>79</sup> *Id.* at \*5

<sup>80</sup> *Id.* at \*6 n.7.

<sup>81</sup> *Feindt*, 2024 WL 1532747, at \*5.

<sup>82</sup> *Id.* at \*6.

One of the experts, Mr. Rosenfeld, justified using an “EPA risk assessment method [that] is not the most widely used,” and his extrapolation from existing data did not undermine the admissibility of his testimony.<sup>83</sup> Another expert, Mr. Spaeth, explained his Bradford Hill analysis, and his conclusion “relied on sufficiently reliable and testable methodology to survive exclusion under rule 702 and *Daubert*.<sup>84</sup> Likewise, in the instant case, the PSC’s experts demonstrated reliable methodology and provided detailed explanations of their Bradford Hill analyses. Judge Wolfson recognized this in her detailed Opinion.

In *Friedman v. Central Maine Power Co.*, No. 2:20-cv-00237, 2024 WL 1327344 (D. Me. Mar. 28, 2024), the court found that the general causation expert opinion was admissible, even though the expert could not quantify the amount of RF radiation exposure from the device at issue.<sup>85</sup> “Both studies [underpinning the opinion] suggest that [the expert’s] theory has been tested, published, and garnered at least some acceptance in the public health community—all indications of reliability under *Daubert*.<sup>86</sup> The studies regarding the health effects of RF radiation “lay the foundation necessary for [the court] to find Carpenter’s opinions on general causation sufficiently reliable to survive CMP’s challenge.”<sup>87</sup>

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<sup>83</sup> *Gonzales*, 2024 WL 836793, at \*3-4.

<sup>84</sup> *Id.* at \*4.

<sup>85</sup> *Freidman*, 2024 WL 1327344, at \*4.

<sup>86</sup> *Id.* at \*4.

<sup>87</sup> *Id.* at \*4.

In *In re: Flint Water Cases*, No. 16-10444, 2024 WL 21786 (E.D. Mich. Jan. 2, 2024), the court found that demonstrating reliable application of Bradford Hill requires an expert to at least “explain 1) how conclusions are drawn for each Bradford Hill criterion and 2) how the criteria are weighed relative to one another.”<sup>88</sup> In *In re: Flint*, the court excluded an expert’s opinion where the expert failed to “explain his use of a single, non-random sample to apply the Bradford Hill analysis,” which was a substantial deviation from standard scientific practice.<sup>89</sup> The problem with the single study was “not that it fails tests of statistical significance but that it is unclear whether it establishes any relevant association in the first place.”<sup>90</sup> The Bradford Hill analysis was insufficient, largely due to his reliance on a single study and his failure “to provide any substantive analysis or explanation for his conclusions.”<sup>91</sup> There are no such problems in the instant case, as the PSC’s experts analyzed data from multiple studies and fully explained their analyses.

The Sixth Circuit *In re: Onglyza (Saxagliptin) and Kombiglyze (Saxagliptin and Metformin) Prods. Liab. Litig.*, 93 F.4th 339 (6th Cir. 2024), affirmed the district court’s exclusion of the plaintiffs’ expert and grant of summary judgment. In so doing, the appellate court held that the expert’s opinion was found to be unreliable because he relied on one randomized

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<sup>88</sup> *In re: Flint Water*, 2024 WL 21786, at \*3.

<sup>89</sup> *Id.* (citations omitted).

<sup>90</sup> *Id.* at \*4.

<sup>91</sup> *Id.* at \*6.

controlled trial to the exclusion of all other human data studies.<sup>92</sup> “In sum, the district court had three good reasons to find Dr. Goyal’s testimony unreliable: (1) improper reliance on SAVOR to the exclusion of all other human studies, (2) unqualified analysis of animal studies, and (3) cherry-picking and inconsistent consideration of the Bradford Hill factors.”<sup>93</sup> Here, there are no reasons to find that the PSC’s experts are unreliable. They are qualified to conduct their chosen methodology. Further, they analyzed multiple studies, considered different study designs, and conducted proper Bradford Hill analyses.

In *Davis v. Lockheed Martin Corp.*, \_\_\_ F. Supp. 3d \_\_\_, No. 6:22-cv-81, 2023 WL 9190261 (M.D. Fla. Dec. 11, 2023), the court excluded expert testimony where the expert’s report did not describe his process. Nor did the report include a categorization of the studies he used, or a Bradford Hill analysis.<sup>94</sup> The court determined that the expert’s methodology was unreliable.<sup>95</sup> In contrast, the PSC’s experts fully analyzed the Bradford Hill factors.

In *In re: Paraquat Prod. Liab. Litig.*, No. 3:21-md-3004, 2024 WL 1659687 (S.D. Ill. Apr. 17, 2024), though the expert’s opinion was about occupational exposure to Paraquat, the court found it unacceptable that the

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<sup>92</sup> *In re: Onglyza*, 93 F.4th at 345.

<sup>93</sup> *Id.* at 348.

<sup>94</sup> *Davis*, 2023 WL 9190261, at \*2.

<sup>95</sup> *Id.* at \*4.

expert redefined "occupational exposure" at least three times.<sup>96</sup> The expert failed to utilize the proper methods of meta-analysis by not documenting how he identified studies for his meta-analysis.<sup>97</sup> In addition, he failed to explain in advance the inclusion/exclusion criteria for studies he used in his analysis, which "suggests that he selected the studies he wanted to include in his meta-analysis and *then* crafted his inclusion/exclusion criteria to justify his decisions."<sup>98</sup> The parties disagreed about which studies provided the most reliable data. However, at the expert admissibility stage, the district court cannot choose between studies.<sup>99</sup> Unlike the experts in *Paraquat*, Judge Wolfson determined that the PSC experts' meta-analysis was reliable.

In *In re: Acetaminophen – ASC-ADHD Prods. Liab. Litig.*, \_\_\_ F. Supp. 3d \_\_\_, No. 22MD3043, 2023 WL 8711617 (S.D.N.Y. Dec. 18, 2023), plaintiffs alleged that prenatal exposure to acetaminophen caused ASD and ADHD. After conducting a *Daubert* analysis, the court found that Dr. Baccarelli's Bradford Hill analysis of multiple associations at once, a transdiagnostic approach, rather than focusing on ASD and ADHD, "raise[d] a question of relevance."<sup>100</sup> The expert's method also "obscured limitations in the scientific literature."<sup>101</sup> The court further found that the expert also chose,

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<sup>96</sup> *In re: Paraquat*, 2024 WL 1659687, at \*23-24.

<sup>97</sup> *Id.* at \*26.

<sup>98</sup> *Id.*

<sup>99</sup> *Id.* at \*33 (citations omitted).

<sup>100</sup> *In re: Acetaminophen*, 2023 WL 8711617, at \*20

<sup>101</sup> *Id.* at \*21.

without explanation, not to use a transdiagnostic approach to his Navigation Guide assessments. Applying different techniques to different bodies of evidence “raises an inference of unreliable application of methodology.”<sup>102</sup> The testimony of Dr. Cabrera was also found to be unreliable, as he “repeatedly cherry picks isolated findings in studies measuring multiple outcomes, ignores inconsistent results, and dismisses the express limitations of study authors.”<sup>103</sup> Finally, the court held the opinions of Dr. Pearson deviated from the principles of scientific reliability, and he made an *ipse dixit* assertion that heterogeneity and outright inconsistency of results don’t ultimately matter” in data analysis.<sup>104</sup>

In *In re: Roundup Prods. Liab. Litig.*, Nos. 16-md-02741 & 20-cv-03719, 2024 WL 3074376 (N.D. Cal. Jun. 20, 2024). Dr. Zhang’s general causation opinion was inadmissible, partly because her meta-analysis involved arbitrary data selection.<sup>105</sup> Further, her “entire engagement with the epidemiological studies is based on her meta-analysis,” which does not equate to a reliable general causation opinion.<sup>106</sup>

### **III. CONCLUSION**

There is no basis upon which to disturb Judge Wolfson’s *Daubert* rulings in this case. This Court opened those rulings to review to the extent that they

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<sup>102</sup> *Id.* at \*22 (citations omitted).

<sup>103</sup> *Id.* at \*36.

<sup>104</sup> *Id.* at \*46.

<sup>105</sup> *In re: Roundup*, 2024 WL 3074376, at \*4.

<sup>106</sup> *Id.*

failed to meet the amended Rule 702 or were contradicted by new science.

Neither of those conditions is met here. Judge Wolfson's *Daubert* rulings properly applied the *Daubert* standards of Rule 702 and should remain in effect.

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Respectfully submitted,

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